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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,774	03/16/2007	Tetsuo Okada	056291-5278	6009
9629 7590 08/02/2010 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004				
EXAMINER				
RAO, DEEPAK R				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/576,774

**Applicant(s)**

OKADA ET AL.

**Examiner**

Deepak Rao

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GA-6)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :20060421, 20061003, 20061005, 20070126, 20081016, 20090326 & 20100426.

### **DETAILED ACTION**

Claims 1-11 and 13-17 are pending in this application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on April 26, 2010 is acknowledged. The traversal is on the ground(s) that the restriction is improper. This is not found persuasive because this application is a national stage application under 35 U.S.C. 371 and lacks unity of invention under PCT Rule 13.2 which states that the applicants are entitled to a compound, a process of preparation of the compound, a composition, and a method of use. The instantly claimed process and the compounds of formula (7) and formula (8) represent patentably independent and distinct inventions as previously pointed out in previous office action. In case of a single claim defining alternatives ("Markush Practice"), 'the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature'. See MPEP, Appendix AI, Annex B.

In the instant case, Inventions I, IV and VI are drawn to distinct processes that involve different reagents and/or result in different products. Inventions II-III and I, IV are related as mutually exclusive species in an intermediate-final product relationship. In the instant case, the intermediate product is deemed to be useful to make other compounds distinct from the instantly claimed compounds and therefore, the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6-11 and 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 21, 2010.

### ***Specification***

The disclosure is objected to because of the following informalities:

The instant specification has figures or drawings within the disclosure, see Figures 1-8 on pages 25-32. These must be submitted as drawings separately.

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. See Figures 1-8 on pages 25-32. These figures must be submitted as drawings. Applicant is required to furnish drawings under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Further, the heading "Brief Description of the drawings" and appropriate description of the drawings will be required.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 03/016317.

The instantly claimed process for the manufacture of the calcium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid (i.e., calcium salt of rosuvastatin) reads on reference disclosed process. The reference teaches a process for preparing calcium salt forms of statins, including rosuvastatin. See the examples of various statins, including rosuvastatin, on page 2 and Examples 7 and 7. The reference teaches a reaction scheme illustrating the process to prepare a calcium salt of a statin on page 18, wherein the starting acetonide compound is reacted with an acid to form the corresponding diol-ester which is then converted to the calcium salt form. The reference inherently teaches the hydrolysis of the ester group prior to the conversion to form the calcium salt.

2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/49014.

The instantly claimed process for the manufacture of the calcium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid (i.e., calcium salt of rosuvastatin) reads on reference disclosed process. The reference teaches the compound of Formula I, tert-butyl (E)-(6-{2-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]vinyl}(4R,6S)-2,2-dimethyl[1,3]dioxan-4-yl)acetate, which is useful in the preparation of the calcium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl](3R,5S)-3,5-

dihydroxyhept-6-enoic acid (see pages 1-2). The reference teaches a process for preparing the above calcium salt by acid hydrolysis of the compound of Formula I to give the corresponding dihydroxy-ester of Formula IV, which is then converted to the calcium salt, see the process steps in pages 4-5.

Receipt is acknowledged of the Information Disclosure Statements filed on April 21, 2006; October 3, 2006; October 5, 2006; January 26, 2007; October 16, 2008; March 26, 2009 and April 26, 2010 and copies are enclosed herewith.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/  
Primary Examiner  
Art Unit 1624**

July 30, 2010